

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UNITED STATES OF AMERICA,

Plaintiff,

V.

WALMART INC. *et al.*,

Defendants.

C.A. No. 20-1744-CFC

RESPONSE IN OPPOSITION TO PARTIAL MOTION TO DISMISS

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INTRODUCTION

The Government alleges that Walmart, as both a dispenser and distributor, exacerbated the opioid epidemic by systematically violating the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (“CSA”). In response, Walmart insists that its corporate structure shields it from the obligation to ensure that its pharmacists did not fill prescriptions Walmart knew were invalid, that the CSA prohibits only the most extreme violations of a pharmacist’s professional practice obligations, that its decision to turn a blind eye to suspicious orders should excuse its obligation to report those orders, and that there are no civil penalties when pharmacists violate professional obligations or distributors fail to report suspicious orders.

These arguments fail. Though the enormous scale of Walmart’s CSA violations may be new, its core duties under the CSA are not. Because of Walmart’s violation of these core duties, both when dispensing and distributing controlled substances, the United States has asserted three claims:

1. **Claim One.** Walmart violated 21 C.F.R. § 1306.04(a) by knowingly filling thousands of invalid prescriptions. Walmart admits that Claim One may proceed with respect to certain allegations that pharmacists knowingly filled invalid prescriptions. But Walmart is also liable for filling prescriptions its compliance team knew were invalid. Walmart may not use its corporate structure

to shield its pharmacists from critical facts and thereby avoid liability for its illegal dispensing. The obligation under the CSA to prevent unlawful fills applies equally to the independent pharmacy with one pharmacist and the chain pharmacy employing thousands. The independent owner-pharmacist, knowing a prescriber is a pill mill, may not lawfully fill that prescriber's invalid prescriptions. And neither may the chain pharmacy.

Walmart also argues—wrongly—that the Government can pursue only claims based on prescriptions that are specifically identified and, further, fails to plead details allowing a plausible inference that pharmacists knowingly filled invalid prescriptions. This mischaracterizes the applicable pleading standard and ignores the extensive facts supporting these allegations.

2. **Claim Two.** Walmart pharmacists violated the CSA's and 21 C.F.R. § 1306.06's requirement to dispense only in the course of professional practice by flouting basic professional rules when they filled controlled-substance prescriptions without resolving red flags of diversion and documenting their resolution. Walmart's argument that this misconduct fell within the course of professional practice is contrary to established law, including *Ruan v. United States*, 142 S. Ct. 2370, 2382 (2022). And contrary to Walmart's argument, this misconduct violates 21 U.S.C. § 829 and thus subjects it to civil penalties. *Id.* § 842(a)(1) & (c).

3. **Claim Three.** Walmart violated 21 C.F.R. § 1301.74(b) by failing to report hundreds of thousands of suspicious orders placed by its pharmacies. Section 1301.74(b) required Walmart to report to DEA each suspicious order it received. Instead of reporting its pharmacies' suspicious orders, Walmart filled such orders without appropriate scrutiny and without reporting them to DEA.

Walmart's interpretation of § 1301.74(b)—that it was required to report only those orders it identified as suspicious—would allow a company to escape reporting obligations by adopting an inadequate monitoring system. And the CSA's text, history, and purpose show that the statute imposes civil penalties for violations of regulatory reporting requirements like § 1301.74(b).

* * *

The CSA obligated Walmart, as a dispenser and distributor, to prevent diversion. If accepted, Walmart's arguments would allow chain pharmacies to fill prescriptions they know are invalid by restricting the information provided to their pharmacists. And its arguments would allow distributors to ignore information about suspicious orders that they unquestionably possess. The Court should reject Walmart's efforts to weaken the CSA and avoid its critical safeguards.

STATEMENT OF FACTS

I. Dispenser Conduct

A. Knowledge of Invalid Prescriptions

Walmart filled thousands of prescriptions it knew were invalid. It did so through the actions of pharmacists who filled prescriptions they knew were invalid, including from known pill-mill prescribers, Am. Compl. (“AC”) ¶¶ 454-75, for dangerous combinations of controlled substances, *id.* ¶¶ 478-89, and for commonly abused “cocktails” and high-dose opioids, *id.* ¶¶ 490-513. These often were accompanied by other red flags, including early requests to fill and cash payments. *Id.* ¶¶ 464, 467, 502, 493, 511. Walmart policies recognized these red flags as indicative of diversion. *Id.* ¶¶ 120, 478-79, 490, 509, 517-18.

Walmart also filled prescriptions its compliance team knew were invalid. Walmart placed responsibility for its pharmacists’ CSA compliance with this team, which exercised control over pharmacists by establishing policies governing dispensing and choosing the tools and information available to pharmacists. *Id.* ¶¶ 92-94, 99-110.

In overseeing CSA compliance, the compliance team received reports when pharmacists refused to fill prescriptions for reasons showing prescribers were acting outside the usual course of professional practice, *id.* ¶¶ 94, 98, 107-08, 127, and had access to stores’ dispensing data that identified pill mills, *id.* ¶¶ 158-61.

Even though team members knew Walmart pharmacists would continue to receive invalid prescriptions from these pill mills, *id.* § II.B.1.a.ii-iii, they took actions they knew would result in filling these invalid prescriptions, *id.* § II.B.1.b. For example, for years, they chose not to share with pharmacists the details about these prescribers. *Id.* § II.B.1.b.i. And when pharmacists identified certain prescribers as pill mills, the team for years prohibited those pharmacists from blanket-refusing their prescriptions. *Id.* § II.B.1.b.ii. When Walmart finally adopted a system for searching refusal-to-fill reports, it did not make that capability widely known, did not include automated alerts in its computer system, and made it difficult to access the information. *Id.* ¶¶ 199-206. Walmart made these decisions despite knowing its pharmacists needed additional information and tools to address diversion. *Id.* § II.B.1.b.iv.

Rather than equipping its pharmacists with information about prescribers that was critical to dispensing decisions, Walmart focused on “driving sales.” *Id.* ¶ 174. The compliance team knew its decisions would result in exactly what occurred: Walmart pharmacists filling thousands of invalid prescriptions. *Id.* § II.B.1.c.

B. Failure to Follow Professional Pharmacy Practice

Pharmacists are professionals trained in dispensing controlled substances. *Id.* ¶¶ 449-452. Their professional obligations require three key steps before filling

controlled-substance prescriptions: identify red flags of diversion, resolve them, and document their resolution. *Id.* ¶¶ 70-76, 547-48. When presented with controlled-substance prescriptions, some Walmart pharmacists failed to fulfill these basic obligations. *Id.* ¶¶ 549-56.

II. Distributor Conduct

Walmart was required to report to DEA suspicious orders of controlled substances. 21 C.F.R. § 1301.74(b). But Walmart knew its order-monitoring system was deficient and did not flag certain suspicious orders. AC ¶¶ 569-609, 618-30. Where Walmart’s system did flag suspicious orders, Walmart often chose not to report or investigate them. *Id.* ¶¶ 610-617, 631-42, 649-53, 675-90, 728-738. Consequently, it failed to report hundreds of thousands of suspicious orders. *Id.* ¶¶ 23, 576.

ARGUMENT

I. Walmart is liable for knowingly filling invalid prescriptions.

As the final step in the supply chain before individuals receive controlled substances, pharmacies have the core obligation to ensure that they fill only valid prescriptions and not ones intended for diversion. That responsibility is reflected in 21 C.F.R. §1306.04(a), which penalizes any “person”—including a corporation, *id.* § 1300.01—that knowingly fills an invalid prescription. *See United States v.*

Appalachian Reg'l Healthcare Inc., 246 F. Supp. 3d 1184, 1189-90 (E.D. Ky. 2017).

Walmart challenges the Government's § 1306.04(a) claim on two grounds. First, it contends that it is not liable for filling controlled-substance prescriptions that compliance team members—but not the filling pharmacists—knew were invalid. Second, it argues that the Government has failed to allege sufficient details regarding Walmart's knowledge and the specific invalid prescriptions. Neither argument has merit.

A. The Government plausibly alleges violations of § 1306.04(a) because Walmart filled prescriptions its agents knew were invalid.

At the motion to dismiss stage, a complaint need only allege sufficient facts to “raise a reasonable expectation” that “discovery will reveal evidence” supporting its claims. *Martinez v. UPMC Susquehanna*, 986 F.3d 261, 266 (3d Cir. 2021) (citations omitted). Here, the AC plausibly alleges that Walmart is liable for knowingly filling invalid prescriptions.

Walmart pharmacists filled prescriptions they knew were issued by pill-mill prescribers or that had obvious red flags of invalidity. AC § II.B.2.b. Walmart concedes that these allegations, if true, state a claim for a violation of § 1306.04(a). Doc. 84 (“Br.”) 16. In addition, Walmart knew certain prescriptions were invalid through its compliance team members, who oversaw pharmacists and whose duties included ensuring Walmart's CSA compliance. *Id.* ¶¶ 92, 99. These team

members learned about prescribers who were “known pill mills,” “did not practice real medicine,” and had “horrendous prescribing practices.” *Id.* ¶ 11. The team chose, for years, not to share this knowledge with pharmacists, resulting in its pharmacists making thousands of dispensing decisions without critical information. And when it finally did place refusal-to-fill forms on a platform accessible to pharmacists, that access was only theoretical because the platform was not easily accessible and was not widely known to or used by pharmacists. *Id.* ¶¶ 201-06. When the team prohibited pharmacists from putting in writing the details about their refusals, they effectively stripped the refusal-to-fill forms of their substance. *Id.* ¶ 131. In addition to depriving pharmacists of critical information, the team adopted policies that steered pharmacists toward decisions to fill, rather than refuse, invalid prescriptions. *Id.* ¶ II.B.1.b.

Walmart argues that the Court must disregard the compliance team’s knowledge and actions. Br. 7-12. That argument is legally incorrect and, if accepted, would have profound ramifications for corporate liability.

Corporations act and know only through their agents. If Walmart were correct that a corporation is liable only if a single agent both possesses the necessary *mens rea* and takes the violative act, Br. 7-10, a corporation could shield itself from liability by isolating certain employees from information known to other employees. In effect, Walmart urges this Court to ignore the knowledge of

the very employees responsible for ensuring Walmart's CSA compliance, including by serving as the repository of information about Walmart's dispensing activities and ensuring that information was provided to Walmart's pharmacists.

Contrary to Walmart's contention, courts have found corporations liable where one employee acts and another employee knows facts revealing the act to be unlawful. For example, in *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 918-19 (4th Cir. 2003), the corporation was held liable under the False Claims Act ("FCA") for submitting a false certification, where an agent involved in a bidding process knew of the existence of a conflict of interest, but another agent submitted a certification that the corporation had no conflicts of interest. The court rejected the argument that the corporation was liable only if a "single agent" both acted and knew the material facts. *Id.* Rather, it was sufficient that a single employee knew of the facts rendering the certification false, regardless of whether he submitted the certification or even knew the company was submitting a certification. *Id.* The court reasoned that a contrary result would incentivize corporations to "segregate[]" the agents submitting certifications from knowledge, "thereby immunizing themselves against FCA liability." *Id.* at 919.

Consistent with that reasoning, numerous courts have found corporations liable by looking beyond the knowledge of the agent taking the violative act. *See*

United States ex rel. Int’l Brotherhood of Elec. Workers Local Union No. 98 v. The Fairfield Co., 5 F.4th 315, 326, 349 (3d Cir. 2021) (under FCA, imputing one employee’s knowledge to entity, where different employee was certifying official and citing *Westinghouse*, 352 F.3d at 919-20 & nn.11-12); *Grand Union Co. v. United States*, 696 F.2d 888, 889-91 (11th Cir. 1983) (cashiers’ knowledge of falsity imputable to corporation, where certifying employee was unaware of fraud); *United States ex rel. Kelly v. Select Specialty Hosp.-Wilmington, Inc.*, No. 1:16-CV-347, 2018 WL 1568874, *6 (D. Del. Mar. 30, 2018) (FCA’s “scienter requirement is satisfied even if the individual who submits the claim does not have knowledge of its falsity”) (citation omitted); *In re Nat’l Century Fin. Enters., Inc.*, 846 F. Supp. 2d 828, 874-75 (S.D. Ohio 2012) (corporate scienter could be found as to agent’s “innocent” misrepresentations where different agent knew of fraud and had opportunity to correct fraudulent materials before they were presented).

The case law also recognizes that an unwitting act by an agent may result in liability for the principal if the principal or a co-agent has relevant knowledge that is not disclosed to the agent. In *In re Sterling*, 933 F.3d 828, 830-34 (7th Cir. 2019), the court held a corporation that engaged an agent to collect a debt but failed to notify the agent when the debt was discharged in bankruptcy violated the discharge order based on the agent’s continued efforts to collect. The court rejected the argument that the corporation was not liable because the agent did not

know about the discharge and concluded that the corporation was liable even in the absence of evidence that it “intentionally withheld notice of the discharge” from its agent. *Id.* at 833-34.

The conclusion that a corporation’s liability does not turn solely on the state of mind of the employee taking the relevant action draws further support from the Restatement of Agency. Agents have a broad duty to provide information to the principal or co-agents, if the information is “material to the agent’s duties.”

Restatement (Third) of Agency § 8.11 & cmt. b. And corporations may not evade liability based on an agent’s unwitting act where another agent has the requisite knowledge, but that knowledge is not shared with the agent who acts for the corporation. *See* Restatement (Third) of Agency § 5.03 cmt. g (principal may be liable to third parties for agent’s innocent misstatement when “the principal withholds relevant information from an agent, knowing that the agent will materially misstate facts ... as a result”); *id.* cmt. c, illus. 9 (knowledge imputed to corporation where agent charged with monitoring information learns of fact but does not communicate it to department taking violative act); *id.* cmt. d(1), illus. 13 (knowledge of false statement in application imputed to corporation where agent with knowledge failed to report it and another agent completed application).

In addition, principals may not evade liability when their agents engage in conduct they expect will cause others to engage in wrongful acts. *See Staub v.*

Proctor Hosp., 562 U.S. 411, 419-20, 422-23 (2011) (corporate liability existed when first agent had discriminatory intent and second agent performed illegal employment action, regardless of second agent’s state of mind, because first agent’s actions were intended to cause and proximately caused the illegal act). “[T]raditional agency principles” impose liability where “the agent intended and was the proximate cause of the adverse result,” even when another person took the ultimate action. *Menaker v. Hofstra Univ.*, 935 F.3d 20, 37-38 (2d Cir. 2019); *see also Staub*, 562 U.S. at 422 n.3 (sufficient to show that agent “believes that the consequences are *substantially certain*” to establish agent’s intent) (emphasis added) (citation omitted).

Further, the doctrine of willful blindness prevents parties from escaping knowledge-based liability by shielding themselves from facts. *See Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011); *United States v. Khoroizian*, 333 F.3d 498, 508 (3d Cir. 2003) (doctrine “allows the jury to impute the element of knowledge to the defendant”) (citations omitted). Thus, a corporation may not evade liability by deliberately shielding employees from critical information.

These authorities belie Walmart’s contention that the requisite knowledge and act must “merge in a particular employee.” Br. 9. And with good reason. If Walmart were correct, a corporation could exploit its corporate structure to isolate

certain employees from information known to other employees and thereby immunize itself from liability. *See, e.g., Sterling*, 933 F.3d at 834 (excusing corporation from liability where agent lacked information “would create a loophole in the law through which [defendant] could avoid liability simply by ... failing to notify [its] agents” of necessary information); *Westinghouse*, 352 F.3d at 919 (“single actor” theory would improperly incentivize corporations to “segregate[]” certifying officials from knowledge to “immuniz[e] themselves against...liability”); *accord* Restatement (Third) of Agency § 5.03, cmt. b (imputation of knowledge “discourag[es] practices that isolate the principal or coagents from facts known to an agent” and use of “agents as a shield against the legal consequences of facts the principal would prefer not to know”). Indeed, such an argument is particularly troubling in the context of this case, where Walmart is asking the Court to ignore, as a matter of law, allegations about the knowledge of the same employees Walmart designated to obtain information about its dispensing activities, communicate information to its pharmacists, and ensure that it complied with the CSA.

Walmart’s arguments to the contrary all miss the mark. Walmart relies upon scattered Restatement provisions to argue that only the knowledge of the single employee acting for the principal is relevant to liability. Br. 7-9. But these

provisions do not suggest that a principal can avoid liability by siloing agents with relevant knowledge.

For starters, Walmart's reading of these Restatement provisions conflicts with the cases discussed above, including *Staub* (a case upon which it relies, Br. 8), which recognizes that corporations may be liable even where the agent who acts lacks the necessary scienter. Walmart claims that *Staub* recognizes that the "mental state of one agent cannot generally be combined with the harmful action of another agent to hold the principal liable for a tort that requires both." 562 U.S. at 418. But the *Staub* Court expressly declined to endorse that contention and acknowledged that *Westinghouse* rejected it. *Id.* In fact, as noted, *Staub* ultimately held that a corporation could be liable based on the state of mind of one employee when a second employee took the relevant action. *Id.* at 422.

Walmart's reading of the Restatement also conflicts with Restatement provisions recognizing that principals can be liable for the acts of unwitting agents. Indeed, one of the key provisions Walmart cites itself recognizes that a principal is bound by the unwitting act of one agent where a second agent has the requisite knowledge and a duty to communicate that knowledge. *See* Restatement (Second) of Agency § 275, cmt. a & rptrs. notes.

Walmart invokes comment d(7) to Restatement (Third) of Agency § 5.03, which it describes as limiting a corporation's liability to the knowledge of "the

individual who took the action” where the law “condition[s] a particular result on whether an individual person had personal knowledge of a fact.” Br. 7-8. But that provision cannot bear the weight Walmart places on it. Comment d(7) applies to statutes or circumstances that explicitly depend on “personal knowledge,” the specific term it repeatedly requires for applicability. The sole case noted in § 5.03 as citing comment d(7), *Mann v. Adventure Quest, Inc.*, 974 A.2d 607, 614 (Vt. 2009), analyzes an insurance policy that uses the specific phrase “personal knowledge.” Section 1306.04 contains no such reference, and there is no basis to interpret any statutory or regulatory reference to “knowledge” as “personal knowledge.”

Moreover, nothing in comment d(7) suggests that it was intended to supersede § 5.03’s recognition of the distinct ground for holding a principal liable for an agent’s unwitting acts where, as here, a knowing principal withholds information from its agent, Restatement (Third) of Agency § 5.03, cmt. g; its discussion of knowledge in the corporate context, *id.* cmt. c (“Organizations are treated as possessing the collective knowledge of their employees ..., when that knowledge is material to the agents’ duties”);¹ or its recognition that d(7)’s

¹ Although the Restatement recognizes that a corporation may be charged with the collective knowledge of its employees, the Government does not rely on a

narrow exception to general principles of imputing knowledge should not be used to undermine regulatory objectives, *id.* cmt. g. Further, comment d(7) recognizes that in the corporate context the relevant personal knowledge includes that of the individual who directed or ratified the action by, for example, “retain[ing] the fruits of the agent’s acts, after knowledge of the facts.” *Maryland Cas. Co. v. Queenan*, 89 F.2d 155, 157 (10th Cir. 1937). Here, Walmart withheld information it knew was pertinent to the repeated dispensing decisions of pharmacists and retained the fruits of the resulting transactions.

Walmart’s reliance on various securities fraud cases fares no better. Those cases recognize that a corporation may be liable if there is a nexus between the agent with the requisite scienter and the making of the fraudulent statements, even if the knowledgeable agent did not make the statements. *See, e.g., Southland Sec. Corp. v. INSpire Ins. Solutions Inc.*, 365 F.3d 353, 366 (5th Cir. 2004) (knowledge of agents who merely “furnish information or language for inclusion therein, or the like” are imputed), *quoted with approval in City of Roseville Emps.’ Ret. Sys. v. Horizon Lines, Inc.*, 713 F. Supp. 2d 378, 402-03 (D. Del. 2010). Here, the Government identifies compliance team members—*i.e.*, those responsible for

collective knowledge theory here, alleging instead that individual Walmart employees held the requisite knowledge. However, the Restatement’s recognition that a corporation may be held liable based on the collective knowledge of its employees further undermines Walmart’s expansive reading of comment d(7).

Walmart pharmacies’ CSA compliance—who individually had information about pill mills that should have led to prescriptions being refused, but that the team members did not share. AC § II.B.1.b, ¶¶ 153, 168, 172. The other cases on which Walmart relies, Br. 9, concern a collective knowledge theory or fraud, which the Government does not assert here.

In sum, even setting aside that pharmacists filled prescriptions they knew were invalid—which Walmart concedes, if true, violates § 1306.04(a)—Walmart is also liable based on its compliance team members’ authority, knowledge, and conduct. This Court should decline Walmart’s invitation to hold that such employees can never serve as the basis for a corporation’s knowledge or liability even where, as here, they had a duty to ensure the company’s CSA compliance. Walmart’s position finds no basis in the law and conflicts with the critical role that the CSA imposes on pharmacies to serve as a safeguard against the misuse and abuse of opioids and other controlled substances. While discovery will illuminate the compliance team’s exact knowledge and roles, the Complaint sufficiently alleges facts to “raise a reasonable expectation” that “discovery will reveal evidence” making the application of these principles of corporate liability appropriate here. *Martinez*, 986 F.3d at 266 (internal quotation omitted). No more is needed at this stage. *Bilek v. Fed. Ins. Co.*, 8 F.4th 581, 588 (7th Cir. 2021) (court need not resolve the bounds of agency claims at the pleadings stage).

B. The allegations that Walmart knowingly filled invalid prescriptions satisfy the pleading standard.

Walmart also disputes the sufficiency of the allegations regarding the degree of alleged knowledge and the invalidity of specific prescriptions. Those arguments fail as well.

Walmart attempts to separate the compliance team from unlawful fills, arguing that the team's refusals to provide guidance to pharmacists proves their ignorance of certain prescriptions' invalidity. Br. 10-11. But the Government alleges in detail that the team had extensive information about prescribers, decided not to provide assistance to and share information with pharmacists, and acted in ways they knew would lead to unlawful fills. AC § II.B.1.b, ¶¶ 227-33. At this stage, where the facts are assumed to be true and are construed in the light most favorable to the Government, Walmart's arguments are not grounds for dismissal.

Walmart then suggests that the Government alleges only that Walmart could have had better CSA compliance policies, not that it knowingly filled invalid prescriptions. Br. 12-13. Walmart cannot recast the allegations of the AC, which plainly alleges that compliance team members knew certain prescribers were pill mills but chose to leave Walmart pharmacists in the dark because of a misplaced focus on sales. AC § II.B.1.a.iii(a). Walmart similarly argues that the AC fails to allege that the team knew that any particular prescription was invalid. Br. 14. But that again ignores the allegations that the team knew these prescribers were pill

mills from pharmacists' reports, AC § II.B.1.c, ¶¶ 171-2, and that *any* controlled-substance prescriptions written by pill-mill prescribers were invalid under § 1306.04(a), AC ¶152.

Walmart next argues that the Government fails to adequately allege willful blindness by failing to allege that the compliance team shielded itself from “the facts about any specific prescription.” Br. 14. But the AC does allege the team shielded itself from facts showing that certain prescribers were pill mills, AC § II.B.1.a.iii, and these facts were enough to reveal the prescriptions' invalidity, *id.* ¶ 152.

Walmart claims that a 2006 DEA policy statement makes it impossible—as a legal matter—to determine that a prescription is invalid based on the prescriber's identity alone because “each case must be evaluated on its own merits in view of the totality of the circumstances.” Br. 14-15 (citing 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006)). Here, the totality of the circumstances known to the compliance team was more than sufficient to conclude that these prescribers' prescriptions were invalid. AC § II.B.1.a. The team also knew, at a minimum through willful blindness, that these invalid prescriptions would continue to be presented to its pharmacies. It thus is unnecessary that the team knew about any particular prescription, at the time it was presented. And Walmart's contention that it cannot be liable because some prescribers were not convicted on some charges or have

avoided other consequences, Br. 15, merely contests as a factual matter the invalidity of these prescriptions and is not a basis to dismiss for failure to state a claim.

Additionally, Walmart challenges the allegations regarding prescriptions filled by pharmacists who knew they were invalid, which it concedes generally state a claim. It argues that the AC must identify every illegal prescription, Br. 16, but a complaint need not include “specific facts” beyond those necessary to state a claim. *Schuchardt v. President of the United States*, 839 F.3d 336, 347-48 (3d Cir. 2016). Even Rule 9(b), which is inapplicable here, does not require pleading every single violation. *See United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 176 (3d Cir. 2019).

Walmart also argues that additional “particularized facts” are necessary to plausibly infer that pharmacists knowingly filled invalid prescriptions. Br. 18. But the allegations detail pharmacists’ fills of prescriptions from known pill mills, AC ¶¶ 454-75, and for dangerous combinations of controlled substances, often with other red flags, *id.* ¶¶ 476-553. Walmart’s own policies recognized many of these red flags as evidence of invalidity. *Id.* ¶¶ 120, 134, 479, 481, 490, 495, 509, 517. Courts have recognized that certain *combinations* of red flags evidence invalidity, *Pharmacy Doctors Enters., Inc. v. DEA*, 789 F. App’x 724, 730-31 (11th Cir. 2019), and that “obviousness” combined with training “is easily sufficient to give

rise to an inference of actual knowledge,” *Kedra v. Schroeter*, 876 F.3d 424, 442-43 (3d Cir. 2017).

Walmart’s speculation that a prescription in one of these categories *might* have a valid purpose is irrelevant because the Government need not preempt “possible explanations” of Walmart’s conduct in response to a motion to dismiss. *Martinez*, 986 F.3d at 267. The Government need only allege the reasons why pharmacists knew certain prescriptions were invalid and filled them anyway.

II. Because it acted outside of the usual course of professional practice, Walmart is subject to civil penalties and injunctive relief.

In addition to prohibiting knowing fills of invalid prescriptions, the CSA and its regulations impose an additional safeguard by requiring both prescribers and pharmacists to act in the course of professional practice when prescribing or filling controlled substances. These restrictions ensure that individuals receive controlled substances only when prescribers and pharmacists follow professional standards. For pharmacists, those standards require three fundamental steps when presented with controlled-substance prescriptions—identifying red flags, resolving those red flags, and documenting their resolution. Walmart pharmacists failed to take those basic steps, and Walmart is liable for civil penalties and injunctive relief.

Walmart argues that its pharmacists did not act outside the scope of professional practice, and that, even if they did, Walmart is not subject to civil penalties for such violations. Walmart is wrong on both accounts.

A. The Government adequately alleges that Walmart pharmacists violated professional practice standards.

Walmart argues that, as a matter of law, pharmacists do not act outside the course of professional practice when they fail to identify and resolve red flags and document their resolution. Br. 24-26. However, professionals act outside the course of professional practice when they depart from “accepted” limits, for example, by failing to satisfy key professional requirements. *See United States v. Moore*, 423 U.S. 122, 142 (1975) (Congress intended to “confine authorized medical practice within accepted limits”); *United States v. Birbragher*, 603 F.3d 478, 485-86 (8th Cir. 2010) (“professional practice” refers to generally accepted medical practice). Neither the CSA nor any other law precisely defines “course of professional practice” or establishes specific criteria. Instead, determining whether acts fall outside the course of professional practice is a question of fact, often involving expert testimony. *See, e.g., Ruan*, 142 S. Ct. at 2382 (professional practice standard asks whether conduct is objectively within accepted limits); *United States v. Shaker*, 827 F. App’x 204, 207-08 (3d Cir. 2020); *United States v. Lovern*, 590 F.3d 1095, 1100 (10th Cir. 2009) (Gorsuch, J.); *United States v. Ahuja*, 209 F. Supp. 3d 489, 494 (D. Conn. 2016). Here, the Government has sufficiently alleged that Walmart pharmacists departed from accepted requirements by failing to identify and resolve red flags or to document the resolution.

Relying on Justice Alito's concurrence in *Ruan*, Walmart argues that pharmacists depart from the course of professional practice only by acting for improper subjective motives. Br. 24-25. But the *Ruan* Court rejected Justice Alito's proposed subjective test. Rather, it explained that the scope of a doctor's prescribing authority is defined by reference to "objective criteria," including the usual course of professional practice, not by the pharmacist's subjective motives or beliefs. 142 S. Ct. at 2381-82.

Relatedly, Walmart contends that falling short of best practices is not practicing outside the usual course. Br. 24-25, 28. But the Government alleges Walmart pharmacists violated *key* professional responsibilities, not merely fell short of best practices. AC ¶¶ 71-76, 545-56. Nor do only the most extreme practices, like selling opioids for cash in a parking lot, Br. 25, violate the usual course of professional practice. *See United States v. Abovyan*, 988 F.3d 1288, 1308 (11th Cir. 2021) (affirming rejection of jury instructions requiring finding that doctor was a "drug dealer"); *United States v. Pellmann*, 668 F.3d 918, 924 (7th Cir. 2012) (conviction appropriate even though doctor was not "drug pusher"). In any event, at this stage, it is unnecessary to hypothesize about the range of pharmacist actions that do and do not violate the usual course of professional practice. The Government adequately alleges that Walmart pharmacists violated the usual course of professional practice by failing to perform key professional

duties to identify, resolve, and document the resolution of red flags. Whether the Government succeeds on this claim is ultimately a question of fact, to be determined once evidence, including expert testimony, has been obtained in discovery.

B. Because Walmart violated § 829, it faces civil penalties and injunctive relief.

Walmart next argues that even if its pharmacists acted outside the course of professional practice, the only remedy under the CSA is revocation of a pharmacy's registration, not civil penalties. Br. 20-23. However, because Walmart pharmacists acted outside of professional standards as required by both 21 U.S.C. § 829 and 21 C.F.R. § 1306.06, Walmart is subject to civil penalties and injunctive relief for violating § 829. *Id.* §§ 842(a)(1), (c)(1), 843(f).

The CSA generally prohibits all conduct involving controlled substances unless authorized. *Id.* §§ 841(a), 822(b). Section 829 prohibits any provision of controlled substances “[e]xcept when dispensed” by a pharmacy holding a valid DEA registration. *Id.* § 829(a), (b); *see also United States v. Bansal*, 663 F.3d 634, 656 (3d Cir. 2011) (§ 829 establishes “[a]n exception to [the CSA’s] blanket prohibition”). The CSA defines “dispense” as “to deliver a controlled substance to an ultimate user ... pursuant to [a prescription]” and “dispenser” as a “practitioner” who delivers the controlled substance. 21 U.S.C. § 802(10). Practitioners, in turn, act as “practitioners,” only when acting “in the course of professional practice.”

Id. § 802(21). Thus, § 829 authorizes the “dispensing” of controlled substances only when done by a “practitioner” acting in the “course of professional practice.” Courts read those provisions together. *See, e.g., United States v. Steele*, 147 F.3d 1316, 1318 (11th Cir. 1998) (“The upshot of all those provisions is that because Steele was acting as an agent of a registered pharmacy, he was authorized to dispense”) (citations omitted).

DEA’s regulations separately establish that dispensing outside the course of professional practice is a violation of § 829. Specifically, 21 C.F.R. § 1306.01 states that the regulations in Part 1306 establish the rules for filling prescriptions under § 829. Section 1306.06, within Part 1306, provides that a controlled-substance prescription may be filled only by a pharmacist “acting in the usual course of ... professional practice.” Thus, § 1306.06’s usual course of professional practice requirement, as with the other regulations within Part 1306, delineates the scope of authorized dispensing under § 829.

Because dispensing controlled substances outside the usual course of professional practice is not permitted by § 829 (both directly through the statutory definitions and through § 1306.06), Walmart is subject to penalties and injunctive relief for doing so. Walmart argues § 829 prohibits only dispensing without a valid prescription. Br. 21. Walmart’s improperly narrow interpretation of § 829 disregards the definition of “dispense” discussed above, and Walmart cites no

supporting authority. Moreover, Walmart's interpretation would lead to the absurd result that, for example, a pharmacist who leaves dangerous controlled substances unattended on a counter for patients to pick up would face no liability under § 829's dispensing authorization, so long as the patients happened to have valid prescriptions.

Walmart further argues that the only remedy to address a pharmacist's failure to act in the course of professional practice is to revoke the pharmacy's registration or threaten revocation. Br. 20. Walmart would limit the Government to taking away pharmacies' authorization to dispense controlled substances altogether (a remedy that may detrimentally impact the surrounding community) or taking no action at all. That is not the law. *Moore*, 423 U.S. at 138 n.15; *see also* 21 U.S.C. § 824(c)(4) (deregistration "shall be independent of, and not in lieu of ... other proceedings").

Walmart also argues that because § 1306.04(a) expressly references civil penalties while § 1306.06 does not, DEA did not intend violations of the latter to give rise to civil penalties. Br. 22. However, numerous courts have imposed civil penalties for violations of other Part 1306 regulations that do not contain an express invocation of civil penalties. *See United States v. Butterbaugh*, 2015 WL 4660096, at *3, *8 (W.D. Wash. Aug. 5, 2015) (§ 1306.05(a)); *United States v. Lopez*, 2017 WL 8182744, at *3 (W.D. Tex. Mar. 20, 2017) (§§ 1306.04 and

1306.05) (Report and Recommendation), *adopted* 2017 WL 8182752, at *1 (W.D. Tex. 2017); *United States v. Salcedo*, 2003 WL 21196843, at *2 (E.D.N.Y. Feb. 19, 2003) (same). These decisions are consistent with DEA’s clear intent that the Part 1306 regulations in total—not just § 1306.04—govern the scope of § 829’s dispensing authorization and the availability of civil penalties.

Walmart further contends that under the Government’s interpretation of § 1306.06, § 1306.04(a)’s prohibition on knowingly filling invalid prescriptions would “have no role left to play” because any § 1306.04(a) violation would also violate § 1306.06 and that the purported overlap would conflict with § 1306.04(a)’s knowledge requirement. Br. 26-27. This ignores the important differences between § 1306.06 and § 1306.04(a) and the purpose of including “knowingly” in § 1306.04(a).

Section 1306.04(a) turns on the prescription’s invalidity, while § 1306.06 turns on pharmacists’ professional practice standards. As a result, certain conduct violates § 1306.04(a) but not § 1306.06, and vice versa. If a pharmacy leaves unwitting pharmacists to fill invalid prescriptions, the pharmacy is liable under § 1306.04(a) but not § 1306.06. Conversely, if pharmacists fail to follow professional standards when dispensing controlled substances, but the prescriptions happen to be valid, they violate § 1306.06 but not § 1306.04(a).

Because § 1306.04(a) turns on the validity of the prescription, the “knowingly” requirement was added to prevent pharmacists from facing liability for unknowingly filling invalid prescriptions. 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971). By contrast, because § 1306.06 focuses on the pharmacists’ own conduct rather than the validity of the prescription and pharmacists are presumed to know the generally accepted limits of their own professional standards, there is no risk of holding an unwitting pharmacist liable.

Walmart points to two unpublished district court decisions holding that § 1306.06 *itself* does not impose penalties. *United States v. Ridley’s Family Markets, Inc.*, No. 1:20-CV-173, 2021 WL 2322478, at *4 (D. Utah June 7, 2021); Order, ECF No. 27, *United States v. Howen*, No. 1:21-cv-00106-DAD-SAB, 16-18 (E.D. Cal. Aug. 9, 2022). But both courts focused on the regulations and failed to consider the separate basis for civil penalties arising from a violation of § 829’s requirement that the dispensing of a controlled substance conform to professional standards of conduct. And both courts erroneously concluded that if pharmacists faced liability under § 1306.06, § 1306.04(a)’s addition of knowledge would be “inoperative.” The Court should decline to adopt their holdings.

Section 1306.04(a) should be read as doing only what it says—clarifying that no penalty may be imposed on a person that fills an invalid prescription for that conduct unless that person knows the prescription is invalid. Section 1306.06

performs an equally important but distinct function by ensuring that pharmacists follow professional practice when dispensing controlled substances. Both requirements must be met for dispensing to comply with the requirements of § 829 and civil penalties and injunctive relief are available if either is violated.

III. The United States plausibly alleges § 1301.74(b) violations that are subject to civil penalties.

In addition to Walmart's violations of critical duties as a dispenser, it violated its duties to stop diversion as a distributor by failing to report suspicious orders. This failure further fueled the opioid epidemic.

The CSA makes it unlawful to negligently fail to file required reports and imposes civil penalties for such failures. 21 U.S.C. § 842(a)(5), (c). As a distributor of controlled substances, Walmart was required to monitor orders and timely report to DEA any "suspicious orders," which include orders of unusual size, pattern, or frequency. 21 C.F.R. § 1301.74(b). When Walmart flagged suspicious orders, it often failed to report them. It also knew it had information showing that other orders were suspicious, but it failed to flag or report them as well. Walmart attempts to excuse its failures to report unflagged orders by arguing that it was required to report only suspicious orders that it actually flagged. It also contends civil penalties do not attach to its violations of § 1301.74(b). Neither argument has merit.

A. Under DEA’s reasonable interpretation of § 1301.74(b), Walmart failed to report suspicious orders.

Section 1301.74(b) requires distributors to operate a system to discover suspicious orders and report them “when discovered by the registrant.” Walmart interprets “when discovered” in § 1301.74(b) to require reporting only when a distributor actually flags a suspicious order. Br. 35. But that reading contravenes the text and purpose of § 1301.74(b). The first sentence of § 1301.74(b) requires each registrant to “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” Given this requirement, a registrant cannot turn a blind eye to suspicious orders, as Walmart repeatedly did. Walmart’s argument—that choosing to ignore suspicious orders insulates it from liability—turns the text of § 1301.74(b) on its head and would perversely allow distributors to evade the reporting requirement entirely if their suspicious order monitoring systems were so flawed as to allow suspicious orders to “escape[] detection” entirely. Br. 35.

Rather, “[t]he purpose of the ‘when discovered’ language is to impose a time period for ‘informing’ [DEA] about a specific suspicious order.” *Masters Pharms., Inc.*, 80 Fed. Reg. 55418, 55478 (agreeing that requiring reports “when discovered” prevents “periodic reports [that] delay” reporting suspicious orders), *pet. for rev. den., Masters Pharms. Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017); *see also Southwood Pharms., Inc.*, 72 Fed. Reg. 36487, 36501 (July 3, 2007) (noting

“reporting requirement exists to provide investigators ... information ... in an expeditious manner” and ruling distributor violated § 1301.74(b) because, *inter alia*, reports were “not timely submitted” “when discovered”). The duty to report attaches as soon as a registrant “has obtained information that an order is suspicious.” *Masters*, 80 Fed. Reg. at 55478; *accord Southwood*, 72 Fed. Reg. at 36501-2 (distributor “repeatedly violated” § 1301.74(b) by “failing to report suspicious orders” after receiving information showing they were suspicious). As DEA has explained, limiting the reporting requirement to orders a registrant itself decided were suspicious would “incentivize registrants to turn a blind eye.” *Masters*, 80 Fed. Reg. at 55477.

Even if § 1301.74(b) were ambiguous, which it is not, DEA’s interpretation is entitled to deference as DEA’s “considered judgment” and “official position” concerning a matter within DEA’s “substantive expertise.” *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2414-17 (2019); *see also Masters*, 861 F.3d at 217 (DEA’s interpretation of what orders were “suspicious” under § 1301.74(b) is entitled to deference).

The Government alleges Walmart knew it had extensive information showing that some orders were suspicious but failed to report them. For example, Walmart knew it was routinely violating its “hard limit” on the number of oxycodone 30mg bottles to ship to a pharmacy, yet did not report those orders as

suspicious. AC ¶¶ 610-17. Additionally, it shipped some orders it had flagged as unusually large without conducting any review but did not report them. *Id.*

¶ 667. Remarkably, Walmart chose not to review many other flagged orders at all, reasoning there were “too many [flagged] orders to review[.]” *Id.* ¶ 669. For some unusually large orders, Walmart “cut” their size and shipped them without reporting them. *E.g., id.* ¶¶ 631-42, 674-90. Pharmacists also raised reports of troubling circumstances reflecting suspicious ordering at Walmart pharmacies, but Walmart did not report those orders either. *Id.* ¶¶ 654-61.

Walmart knew its order-monitoring system failed to flag many other categories of suspicious orders, but Walmart refused to fix it. *Id.* ¶¶ 591-661, 701-48. It also knew its system failed to flag orders of unusual frequencies or patterns, despite § 1301.74(b)’s express requirement to do so. *Id.* ¶¶ 591-97. It knew its system to flag suspicious orders failed to account for the vast number of independent distributors’ shipments to its pharmacies. *Id.* ¶¶ 643-48. Compliance managers acknowledged Walmart needed to fix its system’s serious problems to “avoid DEA enforcement as a result of non-compliance with ... 1301.74(b).” *Id.* ¶ 578. Its extensive distribution-related data, as well as information about its pharmacies’ orders and dispensing, the pill-mill prescribers whose patients filled prescriptions at its pharmacies, and its pharmacists’ reports raising concerns, all

showed these orders were suspicious. *Id.* ¶¶ 562-75. Nevertheless, Walmart failed to report them.

These allegations plausibly allege Walmart violated § 1301.74(b). Notably, even Walmart admits that “some” allegations adequately plead such violations. Br. 36 n.5. At the very least, “determining whether a specific order is ‘suspicious’ and the timing of when it is ‘discovered’ involve questions of fact that will necessarily depend on the totality of individual circumstances.” *In re Nat’l Prescription Opiate Litig.*, 2019 WL 3917575, at *7 n.8 (N.D. Ohio Aug. 19, 2019). This determination cannot be made on a motion to dismiss.

B. Because Walmart violated a CSA-imposed reporting obligation, it is subject to civil penalties.

Walmart asserts it is not liable for civil penalties for violating § 1301.74(b) because § 842(a)(5), which makes it unlawful to negligently fail to file reports “required under this subchapter,” applies only to reports required by statute, not by regulation. Br. 31-35. But the CSA’s text and its “statutory context, structure, history, and purpose,” *Abramski v. United States*, 573 U.S. 169, 179 (2014) (quotation omitted), show Walmart is wrong. Congress intended that the Attorney General promulgate regulations requiring reports and that registrants violating them would face civil penalties.

The Statute. In the CSA, Congress established a “comprehensive” scheme to regulate controlled substances. *Gonzales v. Raich*, 545 U.S. 1, 12 (2005).

Section 842(a)(5), using sweeping language, makes it

unlawful for any person ... to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter

Despite this broad language, Walmart asserts that the phrase “under this subchapter” suggests Congress meant to *exclude* any requirements imposed by regulation. Br. 31. But that phrase alone does not determine whether the statutory provision refers to regulations because “under” is a “chameleon,” whose “diverse renderings ... standing alone [cannot] resolve this case.” *Kucana v. Holder*, 558 U.S. 233, 245 & n.12 (2010). Therefore, “under” “must draw its meaning from its context.” *Id.* at 245 (internal quotation omitted). The context contradicts Walmart’s reading of this phrase.

First, to implement the CSA’s comprehensive scheme, Congress charged the Attorney General with promulgating regulations under the statute, 21 U.S.C. § 821, as are “appropriate for the efficient execution of his functions.” *Id.* § 871(b). Congress described the anticipated regulations as appearing “under” the CSA. *See id.* §§ 811(a) (“Rules of the Attorney General under this subsection”), 822(g) (“regulations under this section”), 825(c) (“prescribe regulations under section 353(b)”), 827(a)(1) (“regulations prescribed under this section”). The Attorney

General promptly adopted regulations, including § 1301.74. 36 Fed. Reg. 7776 (Apr. 24, 1971). Section 1301.74(b) was thus promulgated “under” the CSA, and Congress’s direction for the Attorney General to issue regulations to implement the statutory provisions undermines Walmart’s contention that Congress did not intend civil penalties to apply to violations of regulations.

Second, as noted, § 842(a)(5) broadly references “*any* record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II.” (Emphasis added.) This sweeping language, which includes an extensive list of covered reports, is at odds with Walmart’s suggestion that Congress nevertheless intended to exclude any reporting requirements imposed by regulation.

Third, other penalty provisions that were enacted with § 842 and reference the term “subchapter” suggest that this term includes corresponding regulations adopted by the Attorney General. Section 841 states that conduct is unlawful “[e]xcept as authorized by this subchapter.” If “subchapter” in § 841(a) excludes regulations, conduct authorized by regulation would not be “authorized by this subchapter” and would be subject to prosecution. The Attorney General has repeatedly authorized conduct not specifically authorized by statutory provisions. *See, e.g.*, 21 C.F.R. §§ 1301.12(b)(3) & (4), 1301.23(a) & (b), 1301.24(a) & (b), 1301.26, 1307.11(a), 1317.13. It is unlikely that, in using the phrase “authorized

by this subchapter” in § 841, Congress intended to preclude the Attorney General from recognizing such exceptions.

Section 843 also uses “under this subchapter” in a way that shows an intent to cover regulations. In language like § 842(a)(5), § 843(a)(4)(A) prohibits providing false material information in “any application, report, record or other document required to be made, kept, or filed under this subchapter” It is unlikely that Congress intended to create a loophole by *prohibiting* falsity in statutorily required reports but *permitting* it in regulatorily-required reports. Indeed, courts have upheld § 843(a)(4)(A) convictions where the falsity appeared in information required by regulation. *See United States v. Tull-Abreu*, 921 F.3d 294, 304 & n.6 (1st Cir. 2019); *United States v. Lartey*, 716 F.2d 955, 964-65 (2d Cir. 1983). Thus, both §§ 841 and 843(a)(4)(A) indicate Congress’s intent that regulatorily-imposed requirements be considered requirements “under this subchapter.” Section 842(a)(5) should be read consistently with those provisions.

Finally, Walmart highlights scattered provisions in the CSA referring to “regulations.” Br. 33. But those references just reflect Congress’s intent that the Attorney General, in implementing the CSA, would adopt regulations regarding the CSA generally and regulations regarding specific sections of the statute. None of them evinces any negative implication suggesting Congress meant to *exclude* regulations from § 842(a)(5)’s scope. “[A]ny negative implication ... depends on

context,” and the “*expressio unius* canon” does not arise absent a “fair” inference that Congress “considered” the “unnamed possibility” and “meant” it to signal the exclusion. *Marx v. Gen. Rev. Corp.*, 568 U.S. 371, 381 (2013) (internal quotation omitted). Here, some provisions Walmart cites are unlike § 842(a)(5). *E.g.*, 21 U.S.C. §§ 828(a), 829(f), 880(d)(1). Others were adopted decades later. *E.g.*, *id.* §§ 829(f) (2016), 842(a)(14) (2006). None suggests Congress meant § 842(a)(5) to expansively cover statutory reporting requirements but to exclude regulatory ones.

Walmart suggests that *Kucana* supports its parsimonious reading of “under this subchapter” as referring to only statutory reporting duties, but Congress used “under this subchapter” differently in § 842(a)(5) than in the jurisdiction-stripping provision considered in *Kucana*. That provision covered decisions “*specified* under this subchapter to be” in the Attorney General’s discretion. 558 U.S. at 237 (quoting 8 U.S.C. § 1252(a)(2)(B)(ii)). In concluding that Congress meant to refer to only decisions that *Congress* specified, the Court observed that “the statutory proscription ... speaks of authority ‘specified,’” which “is not synonymous with ‘implied’ or ‘anticipated.’” *Id.* at 243 n.10 (“‘specify’ means ‘to name or state explicitly or in detail’”) (citations omitted). In contrast, § 842(a)(5) is not limited to provisions “specified” by Congress. Significantly, *Kucana* “stress[ed] a paramount factor in [that] decision” was that a contrary reading of the provision

would give the “Executive ... a free hand to shelter its own decisions from abuse of discretion appellate court review.” *Id.* at 252. That concern is absent here.

History. Between 1986 and 2014, Congress repeatedly amended § 842(a) without barring civil penalties for regulatory reporting failures.² During that time, courts interpreted § 842(a)(5) to apply to reporting requirements imposed by regulation. *See United States v. Lerner*, No. 85 C 7593, 1986 WL 8471, at *1 (N.D. Ill. July 30, 1986); *United States v. Stidham*, 938 F. Supp. 808, 813-14 (S.D. Ala. 1996). Walmart identifies no court holding otherwise, for *either* § 842(a)(5) *or* § 843(a)(4)(A).

During the time that Walmart was a distributor and received suspicious orders, DEA issued regulations that affirmed that violations of § 1301.74(b) could result in civil penalties. *See Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008*, 74 Fed. Reg. 15596, 15609 n.47 (Apr. 6, 2009) (violating § 1301.74(b) may “result in civil monetary penalties”). DEA also imposed civil penalties for such violations. *See Masters*, 80 Fed. Reg. at 55422 (distributor paid \$500,000 to settle “claims or potential claims for civil penalties ... for failing to report suspicious orders”).

² 112 Stat. 2681 (1998) (amending § 842(a)(5)); *see also* 102 Stat. 4318 (1988); 110 Stat. 3103 (1996); 120 Stat. 262 (2006); 124 Stat. 2847 (2010); 128 Stat. 2931 (2014).

Although it amended the CSA six times between 1986 and 2014, Congress left the understanding that there are civil penalties for violations of § 1301.74(b) intact. It thereby indicated it accepted this understanding. *Cf. Kucana*, 558 U.S. at 250 (statutory silence on prior regulatory practice leaves “the matter where it was”).

Walmart argues that, before Congress passed the SUPPORT Act, 21 U.S.C § 832, in 2018, § 842(a)(5) must have exempted regulatory requirements from civil penalties, asserting that otherwise the SUPPORT Act’s reporting requirement “accomplished nothing.” Br. 33-34. But the law and facts defeat its speculation. First, “later enacted laws ... do not declare the meaning of earlier law.” *Almendarez-Torres v. United States*, 523 U.S. 224, 237 (1998); *see also Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 839 (1988) (statutory provision’s meaning was not controlled by “the opinion of [a] later Congress as to the meaning of a law enacted 10 years earlier”).

Second, even if the views of the later Congress could be considered, they contradict Walmart’s argument. When that Congress debated the SUPPORT Act (which made other changes to the CSA), it *understood* that civil penalties were *already* available for failures to report suspicious orders. *See, e.g.*, 164 Cong. Rec. S2657, 2680 (daily ed. May 15, 2018) (Sen. Feinstein) (the bill “*increases existing* civil fines for ... distributors who fail to report suspicious orders”) (emphasis

added); 164 Cong. Rec. S6159, 6173 (daily ed. Sept. 17, 2018) (Sen. Cantwell) (“[o]ur legislation *increases* the civil penalties” for “the law that is already on the books about the reporting of suspicious distribution” for opioids) (emphasis added). By enacting the SUPPORT Act, Congress (1) added several new requirements in § 832 (such as data sharing and the establishment of a database); (2) boosted penalties for exactly the conduct in which Walmart engaged; and (3) precluded future agency revocation of § 1301.74(b)’s requirements. These purposes are consistent with the prior availability of penalties and do not support Walmart’s assertion that Congress thought otherwise when it adopted the statute.

Purpose. Walmart’s interpretation of § 842(a)(5) also conflicts with the purpose of the statute. Congress intended the CSA to be implemented through regulations. Walmart’s interpretation would leave DEA with deregistration as the only sanction for failing to report suspicious orders, thereby giving the Government the Hobson’s choice of either revoking a registration or taking no action at all. It is unlikely Congress intended such a result. *Cnty. of Maui, Hawaii v. Hawaii Wildlife Fund*, 140 S. Ct. 1462, 1474 (2020) (rejecting interpretation of

statute in ways that “would ... create a serious loophole in the [regulatory] regime” because such an interpretation “indicates it is an unreasonable one.”³

CONCLUSION

The Court should deny Walmart’s motion.

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³ Walmart’s reliance on the rule of lenity is misplaced. Br. 34. That rule applies *only* if, “after considering text, structure, history, and purpose,” a court can “simply guess what Congress intended.” *Abramski*, 573 U.S. at 188 n.10 (internal quotation omitted). Here, these factors confirm that Congress intended a comprehensive scheme, implemented through a regulatory reporting requirement, the violation of which is prohibited by § 842(a)(5).

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WORD COUNT CERTIFICATION

The undersigned hereby certifies that the foregoing brief contains 8,997 words (exclusive of the cover page, table of contents, table of authorities, and signature block) in Times New Roman 14-point font, counted using Microsoft Word's word count feature.

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